The effect of a social robot intervention on sleep and motor activity of people living with dementia and chronic pain: A pilot randomized controlled trial

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Title

The effect of a social robot intervention on sleep and motor activity of people living with dementia and chronic pain: a pilot randomized controlled trial

Running title-PARO for sleep and motor activity in dementia

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Highlights

- People with dementia living in RACFs are largely inactive and often have sleep disturbances.
- A non-facilitated individual PARO intervention had some effect on sleep duration.
- There was no evidence that PARO had an effect on motor activity.
- Using wearable actigraphy for research in people with dementia is challenging.

Abstract

Objective: To investigate the effect of a social robot intervention on sleep and motor activity in nursing home residents living with dementia and chronic pain.

Method: A pilot randomized controlled trial was conducted with 41 residents from three Australian nursing homes. People living with dementia and chronic pain were randomized into either a 30-minute daily social robot (PARO) condition or a usual care condition during six weeks. Sleep and motor activity were assessed by actigraphy at four-time points: week 0 at baseline, week one, week six, and after the intervention. Data were reduced into daytime (8:00am - 7:59pm) and night-time (8:00pm - 7:59am) summaries. Change scores for each time point compared to baseline were computed for data analysis and the generalized estimating equation model with imbalanced baseline values added as covariates were performed.

Results: At week one, residents in the PARO group had a greater increase in the night sleep period (1.81, 95% CI: 0.22 to 3.84, $p = 0.030$, Cohen's $d = 0.570$). At week six, residents in the PARO group showed a greater increase in daytime wakefulness (1.91, 95% CI: 0.09 to 3.73, $p = 0.042$, Cohen's $d = 0.655$) and a greater reduction in daytime sleep (-1.35, 95% CI: -2.65 to -0.05, $p = 0.040$, Cohen's $d = 0.664$). No significant results were found for motor activity.

Conclusion: PARO could be a potentially beneficial therapy to improve sleep patterns for nursing home residents living with dementia and chronic pain, but the effect of PARO on motor activity needs further research.

Australian New Zealand Clinical Trials Registry (ACTRN12618000082202).

Keywords: dementia, pain, sleep, motor activity, actigraphy, nursing homes

1. Introduction

Sleep disturbances and physical inactiveness are common in people with dementia living in residential aged care facilities (RACFs). Up to 70% of individuals with dementia are affected by disturbed sleep [1] and people with dementia living in residential aged care facilities (RACFs) are reported to spend around 85% of their daytime physically inactive [2]. Disturbed sleep and decreased physical function can have significant consequences, such as greater risks of injuries [3] and increased caregiver burden [4]. Pain is generally linked to sleep disturbances [5] and may inhibit physical activity [6]. Over half the people with dementia living in RACFs are affected by pain [7]. Evidence suggests that appropriate pain management may improve sleep [8] and physical functions of residents with dementia [9].

Despite the increasing use of pain medications, over 50% of residents living in RACFs are affected by clinically relevant pain that may trigger behavioral and psychological symptoms [10]. There is some evidence that psychosocial interventions may be effective in pain alleviation for people with dementia [11]. Social robots, which are defined as an artificial agent embodied with features of a human or an animal, has been identified as an approach to meet the mental health needs of older adults through interaction or information exchange [12]. Social robots are reported to improve the well-being of a variety of population, especially for older adults with dementia [13]. Sleep quality and motor activity

are important indicators of well-being, but until now have not been widely measured as effective outcomes in studies using social robots. Several studies suggest that social robot interventions may have the potential to positively affect sleep parameters for people with dementia. For example, the robotic seal PARO, has been reported to improve sleep behaviors for people with dementia [14]. Studies with older women showed that living with a communication robot tended to increase nocturnal sleep hours and decrease the difficulty in maintaining sleep [15]. Additionally, one study found that participants in a PARO group had a greater reduction in night-time motor activity than the usual-care group [16]. Although studies have demonstrated potential benefits of social robots for people with dementia, none of these studies reported its effect on people with both dementia and chronic pain from randomized controlled trials. While chronic pain may be a risk factor for sleep problems and physical functions in older persons, PARO is hypothesized to have the potential to reduce pain and subsquently lead to improvements in sleep and motor activity for people with dementia and chronic pain living in RACFs.

2. Methods

2.1 Design

This study was performed as part of a pilot randomized controlled trial, exploring the feasibility and effect of a social robot (PARO) intervention for people with dementia and chronic pain living in RACFs in Australia from January 2018 to January 2019 [17]. Participants were randomized into either a daily (Monday to Friday) 30-minute individual, non-facilitated PARO condition or a usual care condition (e.g., music, bingo, activities, etc.) for six weeks by a computer-generated random list. Given the nature of psychosocial interventions, both participants and researchers were not blinded to the random allocation. Sample size calculation was based on the primary outcome of observational pain levels [17]. Our previously published paper of the study primary outcomes indicated the PARO

intervention shows promise in reducing pain and as needed medications for individuals with dementia in RACFs [17]. In this paper, findings from the study's secondary outcomes of sleep and motor activity are presented. Due to the lack of studies in this area, preliminary evidence from this pilot RCT may help determine the effect of the PARO intervention on sleep and motor activity in people with dementia and chronic pain living in RACFs and to inform the required sample size for a larger trial.

2.2 PARO

PARO, a therapeutic robotic seal, is a psychosocial intervention and can be described as a socially assistive robot to enhance communication, socialisation, and emotional connection for people living with dementia [18]. PARO has the appearance of a baby harp seal and is covered with artificial fur. It has four senses of sight, hearing, balance and tactile to respond and communicate with users by moving or making a sound. Interacting with PARO can make people feel happy and they may enjoy having PARO for a companion, which reflects the therapeutic effect of PARO on users [18].

2.3 Sample

Convenience sampling was used to recruit participants who met the following criteria**:**

(1) Aged 65 years and older; (2) Participants must have been diagnosed with some form of dementia, or probable diagnosis of dementia; (3) Being prescribed pain medications or an indication of chronic pain. For those who cannot self-report pain, proxy reports of pain from registered nurses (RNs) for the previous week were obtained; (4) Demonstration of perceived senses for interaction with PARO, such as vision, hearing or touch; and (5) Living in a facility for more than three months.

Participants were ineligible for participation if they met at least one of the following criteria: (1) Diseases such as acute exacerbation of chronic obstructive pulmonary disease or renal failure that required residents to be admitted to hospital frequently; (2) Terminal

illnesses where the resident is in the final palliative stage; (3) A diagnosis of a major mental illness such as schizophrenia; (4) Infectious diseases or with an open wound that was unable to be covered.

2.4 Outcome measures

Socio-demographic information of participants was assessed at baseline. Cognitive status was assessed using the Mini-Mental State Examination (MMSE) [19]. Medical conditions, dementia subtypes and medication use were audited from the residents' medical records. Researchers collected proxy assessments of pain history (e.g., pain frequency, onset, intensity, locations, and nonpharmacological therapies) through structured interviews with the nursing staff who had regular contact with the resident.

Given the challenges of measuring sleep and motor activity in people with dementia, the use of actigraphy was deemed to be feasible and acceptable in people with dementia [20, 21]. It is an objective measurement of sleep patterns and motor activity while avoiding reliance on over- or under-estimated reports from caregiver [21, 22]. The actigraphy used in this study was the SenseWear Professional 8.0 activity armband (Body Media, Inc) [23]. It is a wireless, slim, nonintrusive armband which is placed on participants' upper non-dominant upper arm over the tricep muscle and held in place by a Velcro armband. Several sensors related to sleep and motor activity are incorporated into this device. Data was collected over 24 hours with participants on four occasions: (1) Sunday of week 0 before the intervention (baseline); (2) Monday of the first week for intervention (at week 1); (3) Friday of week six for intervention (at week 6); and (4) Saturday of week six (after), removing only for bathing or discomfort. Care workers were trained on how to put on and take off the armband. Instructions for administering the SenseWear were also placed in the residents' rooms and in the nurses' office to explain the use of the actigraph and objectives of the study. The researcher checked the skin of the resident daily to ensure that the armband did not cause a

tear, lesions, or rash and swelling due to allergy.

According to a previously published study [16], data at each time point were reduced into daytime (8:00am - 7:59pm) and night-time (8:00pm - 7:59am) summaries. Outcomes were changes in participants' levels of sleep and motor activity at week six. Sleep patterns were measured by the time spent (hours) (1) lying down; (2) awake; and (3) sleep (light sleep, deep sleep and very deep sleep). Motor activity was measured by (1) skin temperature; (2) distance walked (kilometers); (3) number of steps taken; (4) time spent (hours) in at least light physical activity (>1.5 metabolic equivalent of task); and (5) energy expenditure (kcal). Short term and prolonged effects at week 1 and week 6 were also examined respectively.

2.5 Data analysis

All data analysis was conducted using IBM SPSS Statistics software 25.0. The last observation carried forward was used to manage missing data for outcomes. SenseWear data were extracted using SenseWear software and then uploaded to a password protected PC for analysis. The generalized estimating equation (GEE) model with imbalanced baseline values added as covariates was used to explore the effect of PARO interventions on outcomes. Change scores from baseline to each time point with 95% confidence intervals (CIs) between two groups were computed for analyses. Cohen's *d* for effect size (0.20 = small effect, 0.50 = moderate effect, and 0.80 = large effect) [24] was calculated and statistical significance was set at $p<0.05$.

3. Results

Forty-three residents from three RACFs were randomly allocated to the intervention group (n=21) and the control group (n=22). Two residents from the control group refused to put on the armband, and they were excluded from the data analysis. The attrition rate of participants was 7.0% with three drop-outs due to death (n=2) and loss of interest (n=1). No adverse events (e.g., skin tear, allergy, etc.) were recorded during the data collection. Figure 1 shows

the CONSORT flow diagram.

<Inert Figure 1 here>

3.1 Demographic comparisons between the two groups

The percentage of females is significantly higher (p=0.033) in the intervention group (85.7%) than in the control group (55.0%). Apart from gender, the demographics and medical conditions of participants in the two groups were comparatively similar before the intervention (Table 1).

<Inert Table 1 here>

3.2 Baseline outcome measures between the two groups

Compared to residents in the control group at baseline, residents in the PARO group had fewer daytime step counts (p=0.039), shorter night-time awake hours (p=0.030) and less daytime (p=0.032) and night-time (p=0.039) energy expenditure (Table 2).

<Inert Table 2 here>

3.3 The effect of PARO intervention on sleep and motor activity

The effect of the six-week PARO intervention

At the end of the six-week PARO intervention, compared to the control condition, the duration of daytime wakefulness was significantly increased (1.91, 95% CI: 0.09 to 3.73, p=0.042, Cohen's d=0.655) and the duration of daytime sleep was significantly decreased (-1.35, 95% CI: -2.65 to -0.05, p=0.040, Cohen's d=0.664) in the PARO group, especially in the reduction of daytime light sleep (-1.27, 95% CI: -2.36 to -0.19, p=0.023, Cohen's d=0.746) (Table 3). There were no significant differences in daytime motor activity and all night-time outcomes.

Short-term effect of PARO intervention

After one session of PARO intervention at week 1, the increase in the duration of light sleep at night was significantly higher in the PARO group when compared to the control group

(1.81, 95% CI: 0.22 to 3.84, p=0.030, Cohen's d=0.570) (Table 3). However, no significant differences were found in daytime outcomes.

Sustained effect of PARO intervention

There were no significant differences in the change of sleep and motor activity between the PARO and control group after the six-week intervention (Table 3), which means that there was insufficient evidence to support the sustained effect of the PARO intervention on any outcomes.

<Inert Table 3 here>

3.4 The use of SenseWear armband with people with dementia

The SenseWear armband was not well tolerated in people with dementia, with just seven participants having a valid wear-time of ≥10 hours for four measurements. The average length of wear-time was 10.16 (± 2.68) hours during day time and 9.73 (± 4.2) hours at night. The main reason for low compliance was that residents took off the armband due to their unwillingness to wear the armband, especially at night. All devices were returned intact with no evidence of damage but an unknown technical issue in the extract of data was experienced with one device. Moreover, over half of the participants had problems with mobility and used a walker or were fully bedbound and this may have had an impact on the accuracy of detection of step counts.

4. Discussion

To our knowledge, this was the first attempt to assess the effect of PARO on sleep and motor activity for individuals living with dementia and chronic pain. An individual, non-facilitated interaction with PARO was found to have some effects in reducing daytime sleep and improving night-time sleep when compared with a usual care routine. However, no significant results were found for motor activity. These results suggest that PARO may have the potential to improve sleep in residents experiencing chronic pain and dementia.

Some studies have demonstrated the effect of interacting with robots on sleep patterns. For example, a robot at the RACF could provide the opportunity for residents to stimulate their day-time activity and thus help residents develop better daytime and night-time sleeping patterns [25]. Results from interviews with residents with dementia indicated that interacting with PARO made people feel calm and this could help with their sleep [26]. Similarly, care staff reported that a robotic cat may bring feelings of calm and safety for residents and thus may be used as an alternative for sedative medication [27]. This may be explained by the fact that social robots may have similar benefits to live pets and their presence could provide a sense of safety and security, which could promote sleep [28]. However, two previous studies [16, 29] found no significant effect of PARO on the sleep of people with dementia.

Several reasons regarding the participants and the intervention format may contribute to these inconclusive results. The trial population in this current study had a lower level of mobility due to chronic pain and a lower level of cognitive function at baseline than the population of larger published RCTs [16, 29]. The degree of cognitive impairment could impact the intervention efficacy of PARO on participants but the relationship between the severity of cognitive impairment and responses from using social robots remains unclear [13]. Another reason that results may have diverged from past trials is the frequency and duration of the intervention. A daily 30-minute intervention for five days a week was applied in this study, which is more frequent and longer than previous studies with only 15-minutes for three sessions per week [16] or 10-minute for two sessions per week [29]. There is still currently an absence of consensus on the appropriate intervention dose of PARO intervention for people with dementia which could impact on the intervention efficacy of PARO. The challenges of using social robots in clinical practice have been reported, including the high cost (US$6000) [30] and a lack of skills and confidence to the uptake of social robots in daily practice [31].

Previous research on PARO was researcher-centered [30] and stakeholders including clinicians, families, policymakers and organizational leaders need to be engaged to identify strategies to enable the successful translation of robotic technology into practice.

It is challenging to maintain the compliance of wearing the SenseWear armband for people with dementia for a prolonged period. A systematic review reported that the issue of repeated removal of actigraphy devices, in particular at night, often occurs in studies involving people with dementia [21]. Therefore, low compliance with wearing the devices results in a large source of data loss and creates interpretation issues. Researchers generally require at least 10 hours of wear time to ensure accurate estimates of motor activity [22]. However, it should be noted that this is based on younger participants who were cognitively healthy, and therefore, there was no wear time requirement in this study and this requirement may differ in older adults with dementia. Moreover, the armband was unable to detect the movement of arms and measure step counts when people are using a walker. Some researchers recommend attaching the device to the hip via an elastic belt to measure motor activity and improve compliance in people with dementia [32]. However, the attachment methods may depend on the design of the actigraphy or the study outcomes, as well as feasibility within the study population. It is therefore recommended to develop a protocol of using device-based sleep and activity monitoring tailored to people with dementia in terms of placement site, methods of attachment and the number of days of recording. Approaches are needed to improve compliance with protocols by avoiding the removal of the device and increase the sensitivity to detect sleep and motor activity of cognitively impaired subjects.

This study has several limitations. First, this trial was conducted with a small sample of 41 residents with dementia and chronic pain living in RACFs in Australia, and results may not be generalizable to people in other settings with different conditions. Moreover, future studies with a larger number of participants would allow for subgroup analysis to investigate

personal (e.g., impaired mobility), environmental (e.g., secure dementia care units) and organizational factors (e.g., exercise programs) relating to physical activity [33] and sleep [34] in people with dementia living in RACFs. Second, although the duration of wearing the actigraphy was comparable between the intervention and usual care groups with an average on-body time of 10 hours (out of 12 hours), results should be interpreted with caution as longer wear-time may produce different results. Third, only a 24-hour period was recorded at each time point and this may reduce the internal validity and reliability of the results considering the high levels of individual variations in daily physical activities. Evidence suggests at least three consecutive days of recordings are necessary to accurately estimate daily physical activity in older adults [35]. Despite the control of gender in the analysis, the imbalance of gender ratio between two groups may bring bias to results as studies suggest that females may respond and interact more positively to PARO compared to males [36]. Finally, although the blinding of participants and researchers were compromised in this study, this might not significantly affect objective outcomes.

5. Conclusion

PARO could potentially improve sleep for long-term care residents with dementia and chronic pain. Whether this type of intervention could be effective in motor activity requires further research. However, the small sample size may have limited the power and suggests the need for larger-scale trials. This study also highlights the challenges of using SenseWear armband to collect objective data with cognitively impaired residents and further development of such devices is needed.

Author contributions

All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

Lihui Pu made substantial contributions to the conception and design of the work, conducted the analysis, wrote the initial draft, and approved the final version of the paper.

Wendy Moyle made substantial contributions to the conception and design of the work, assisted with interpretation of the data, provided critical review of the initial draft, and approved the final version of the paper.

Cindy Jones made substantial contributions to the conception and design of the work, assisted with interpretation of the data, provided critical review of the initial draft, and approved the final version of the paper.

Michael Todorovic made substantial contributions to the design of the work, assisted with interpretation of the data, provided critical review of the initial draft, and approved the final version of the paper.

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Conflict of interest

The authors declare no other conflicts of interest.

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Ethical Statement

The study was reviewed and approved by the Griffith University Human Research Ethics Committee (2017/774) and study sites. This study was also prospectively registered with the Australia New Zealand Clinical Trials Registry (ACTRN12618000082202). Written informed consent was obtained from participants' legal representatives prior to the inclusion.

Research data (data sharing and collaboration)

There are no linked research data sets for this paper. The authors do not have permission to share the data.

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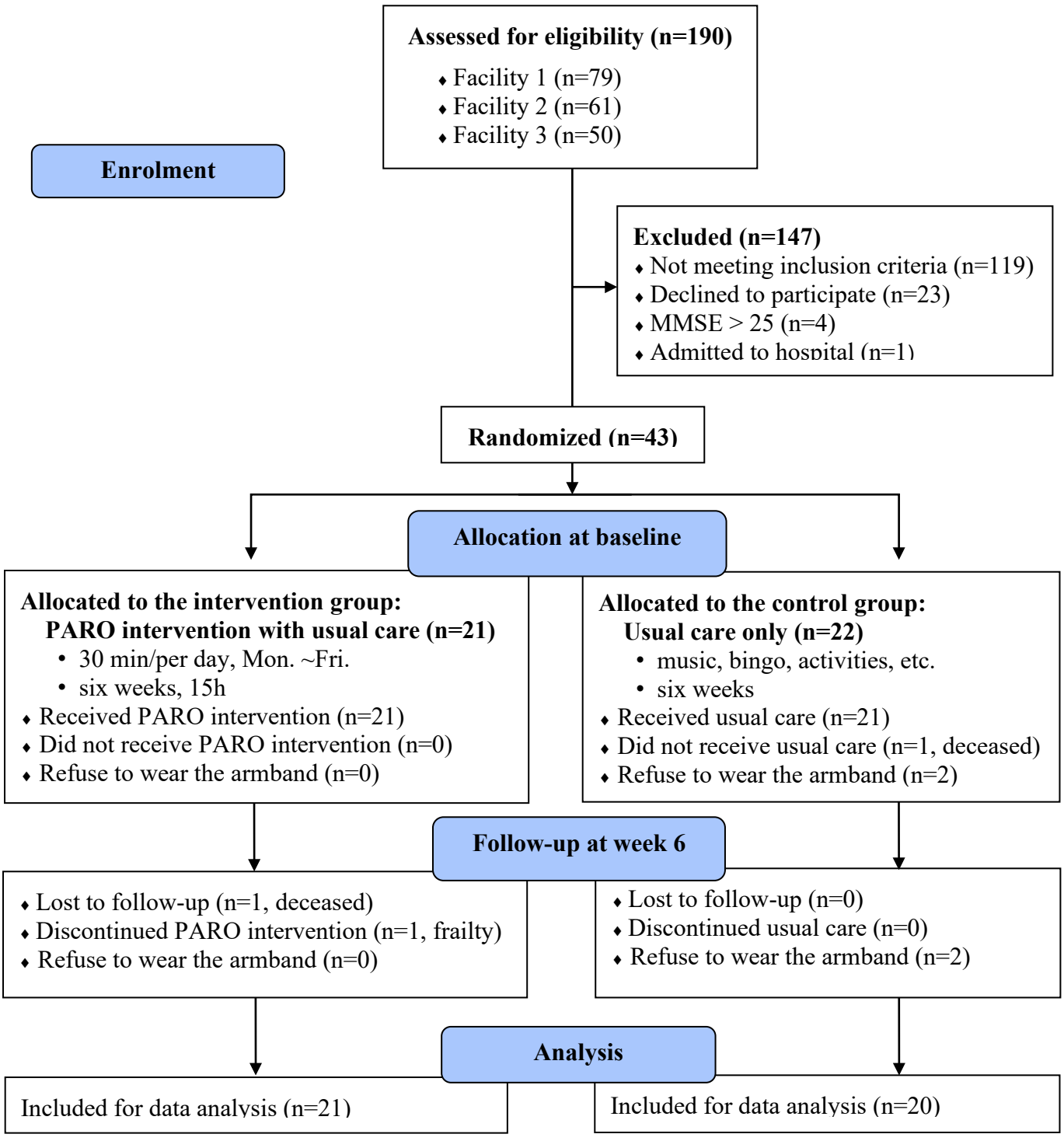

Figure 1 CONSORT flow diagram

Table 1 Demographics and medical conditions of participants with SenseWear data

Variables	Control group (n = 20)	Intervention group (n = 21)	*p* value
Age[*]	85.50±6.02 86.5 (72, 93)	86.48±8.81 90 (65, 97)	0.234[†]
Gender			
Female	11 (55.0%)	18 (85.7%)	**0.033**[‡]
Male	9 (45.0%)	3 (14.3%)	
Dementia subtypes			0.766[§]
Alzheimer's disease	7 (35.0%)	9 (42.9%)	
Vascular dementia	3 (15.0%)	2 (9.5%)	
Frontal-temporal dementia	1 (5.0%)	0 (0.0%)	
Dementia unspecified	9 (45.0%)	10 (47.6%)	
Living unit			0.354[‡]
Secure dementia unit	9 (45.0%)	13 (61.9%)	
Facility unit	11 (55.0%)	8 (38.1%)	
Facility room-type			1.000[§]
Single room	18 (90.0%)	18 (85.7%)	
Shared room	2 (10.0%)	3 (14.3%)	
Activity level			0.280[§]
Ambulatory	1 (5.0%)	4 (19.0%)	
Assistive devices	11 (55.0%)	6 (28.6%)	
Wheelchair	3 (15.0%)	3 (14.3%)	
Bedridden	5 (25.0%)	8 (38.1%)	
Walking exercise, yes	10 (50.0%)	15 (71.4%)	0.160[‡]
Admission month[*]	33.2±29.32 25 (3, 100)	24.8±23.68 16 (3, 99)	0.449[†]
MMSE[*]	11.55±8.06 (0, 23)	7.71±7.84 (0, 24)	0.114[†]

Variables	Control group (n = 20)	Intervention group (n = 21)	*p* value
MMSE <11	9 (45.0%)	15 (71.4%)	0.086†
BMI*	25.10±7.04 (16.4, 49.6)	22.12±4.93 (11.83, 35.8)	0.134†
The intensity of pain			0.486§
No pain	1 (5.0%)	7 (33.3%)	
Mild	8(40.0%)	6 (28.6%)	
Moderate	11 (55.0%)	7 (33.3%)	
Severe	0 (0.0%)	1 (4.8%)	
Nurse-estimated pain score*	3.05±2.09 3 (0, 8)	3.24±2.49 3 (0, 9)	0.915†
MQS score for medication*	14.54±8.59 13.5 (2.2, 36.9)	14.56±7.86 12.4 (3.8, 33.7)	0.896†

Note. * values presented as Mean ± *SD*/median (range), Bold values are statistically significant ($p < .05$).
Abbreviations: SD, Standard Deviation; MMSE, Mini-Mental State Examination; BMI, Body Mass Index; MQS, Medication quantification scale-III.
†value was calculated with Mann-Whitney *U* test
‡ value was calculated by Chi-square test
§value was calculated by Fisher's exact test
‖value was calculated with independent *t*-test

Table 2 Mean scores and standard deviations for SenseWear outcomes at four-time points (n=41)

	PARO group (n=21)				Usual care group (n=20)			
	Baseline	**Week 1**	**Week 6**	**After**	**Baseline**	**Week 1**	**Week 6**	**After**
SenseWear, daytime								
Time on body (hrs.)	9.46 (1.99)	11.15 (1.87)	10.49 (2.73)	10.62 (2.24)	9.47 (1.86)	10.23 (3.08)	10.46 (2.58)	9.89 (3.59)
Skin temperature (°C)	33.27 (1.10)	33.23 (0.93)	32.55 (2.41)	33.12 (1.27)	33.30 (0.76)	32.72 (1.37)	32.96 (1.49)	33.24 (1.17)
Distance (kilometers)	0.03 (0.09)	0.05 (0.23)	0.05 (0.200	0.03 (0.13)	0.03 (0.10)	0.04 (0.11)	0.03 (0.08)	0.04 (0.10)
Step counter (n)	**88.33 (209.01)**	115.95 (333.24)	100.00 (248.86)	91.00 (225.52)	**188.10**† **(288.74)**	187.85 (311.72)	135.35 (220.34)	194.15 (361.38)
Lying down (hrs.)	2.49 (3.37)	2.96 (3.73)	2.60 (3.02)	2.26 (2.37)	0.68 (1.05)	1.64 (2.79)	2.38 (3.36)	1.59 (2.77)
Average MET	1.22 (0.11)	1.21 (0.11)	1.19 (0.21)	1.15 (0.10)	1.25 (0.16)	1.24 (0.18)	1.17 (0.14)	1.20 (0.19)
Physical activity (hrs.)	1.07 (0.97)	1.17 (1.28)	0.84 (1.29)	0.71 (0.93)	1.45 (1.25)	1.51 (1.42)	0.95 (0.99)	1.12 (1.36)
EE (kal)	**2789.06 (877.68)**	3346.11 (1240.16)	3069.60 (1339.13)	2993.37 (1087.09)	**3046.49**‖ **(901.48)**	3681.54 (1553.31)	3553. 87 (1364.33)	3561.08 (1756.06)
Awake (hrs.)	7.45 (3.35)	8.75 (3.79)	8.59 (3.45)	9.00 (3.26)	9.01 (2.20)	9.29 (3.27)	8.66 (3.28)	8.84 (4.09)
Total sleep (hrs.)	2.01 (2.93)	2.40 (3.48)	1.90 (2.80)	1.61 (2.18)	0.47 (0.90)	0.95 (1.72)	1.80 (2.78)	1.05 (2.55)
Light sleep (hrs.)	1.62 (2.43)	1.77 (2.61)	1.30 (1.80)	1.34 (1.82)	0.33 (0.55)	0.66 (1.02)	1.38 (2.03)	0.73 (1.74)
Deep sleep (hrs.)	0.24 (0.53)	0.33 (0.71)	0.37 (0.75)	0.16 (0.22)	0.10 (0.25)	0.19 (0.56)	0.28 (0.47)	0.22 (0.56)

	PARO group (n=21)				Usual care group (n=20)			
	Baseline	**Week 1**	**Week 6**	**After**	**Baseline**	**Week 1**	**Week 6**	**After**
Very deep sleep (hrs.)	0.15 (0.31)	0.33 (0.71)	0.23 (0.50)	0.11 (0.28)	0.04 (0.15)	0.19 (0.56)	014 (0.46)	0.11 (0.31)
SenseWear, night-time								
Time on body (hrs.)	9.33 (4.25)	10.85 (2.73)	9.66 (4.24)	9.89 (3.98)	9.80 (4.14)	10.31 (3.91)	10.61 (3.65)	10.08 (4.05)
Skin temperature (°C)	33.33 (1.27)	32.35 (7.44)	31.64 (7.52)	33.66 (1.21)	33.41 (1.16)	31.85 (7.57)	31.62 (7.56)	33.42 (1.29)
Distance (kilometers)	0.00 (0.02)	0.00 (0.00)	0.00 (0.14)	0.00 (0.00)	0.03 (0.12)	0.01 (0.03)	0.00 (0.02)	0.01 (0.03)
Step counter (n)	25.67 (55.89)	41.71 (66.66)	97.10 (336.36)	25.81 (50.61)	134.55 (248.52)	85.10 (129.96)	98.02 (129.27)	77.75 (179.63)
Lying down (hrs.)	7.06 (4.42)	8.85 (3.12)	7.35 (4.24)	6.72 (4.12)	5.53 (4.12)	6.41 (3.61)	6.31 (4.00)	6.34 (3.49)
Average MET	1.15 (0.31)	1.00 (0.26)	1.05 (0.35)	1.13 (0.32)	1.11 (0.16)	1.01 (0.28)	1.03 (0.30)	1.16 (0.47)
Physical activity (hrs)	0.26 (0.43)	0.35 (0.54)	0.24 (0.32)	0.27 (0.36)	0.57 (0.83)	0.48 (0.54)	0.64 (0.92)	0.55 (0.87)
EE (kal)	**2362.80 (1098.87)**	2764.96 (970.96)	2443.70 (1095.77)	2423.96 (958.03)	**3034.74**† **(159.83)**	3089.57 (1420.46)	3260.62 (1517.55)	3099.87 (1459.16)
Awake (hrs.)	**3.78 (3.17)**	3.74 (2.53)	3.92 (3.07)	4.93 (3.53)	**5.83 (3.82)**†	5.75 (3.34)	6.08 (3.92)	5.52 (3.26)
Total sleep (hrs.)	5.55 (4.31)	7.11 (3.30)	5.74 (4.10)	4.95 (4.13)	3.97 (3.73)	4.56 (3.24)	4.53 (3.63)	4.56 (3.22)
Light sleep (hrs.)	3.64 (2.72)	5.72 (2.58)	4.24 (2.95)	3.29 (2.80)	2.87 (2.61)	3.14 (1.8 9)	3.08 (2.32)	2.91 (1.84)
Deep sleep (hrs.)	1.05 (1.25)	1.04 (1.08)	0.81 (1.28)	1.05 (1.23)	0.56 (0.79)	0.89 (1.26)	1.01 (1.79)	1.03 (1.39)

	PARO group (n=21)				Usual care group (n=20)			
	Baseline	**Week 1**	**Week 6**	**After**	**Baseline**	**Week 1**	**Week 6**	**After**
Very deep sleep (hrs.)	0.87 (1.37)	0.35 (0.55)	0.69 (0.96)	0.62 (1.05)	0.54 (0.82)	0.53 (0.73)	0.44 (0.56)	0.63 (0.97)

Abbreviations: hrs, hours; mins, minutes; EE, energy expenditure; MET, metabolic equivalent; physical activity was calculated as the average time (mins) spent in activities with an estimated EE ≥ 1.5 metabolic equivalents (METs), which is at least light physical activity.
Bolded values indicate statistically significant results at week 0 for the level of $p<0.05$.
[†]Values were calculated with Mann-Whitney *U* tests; [‖]Values were calculated with Independent *t*-tests.

Table 3 The effectiveness of PARO intervention on SenseWear outcomes[#] (n=41)

Outcomes	PARO intervention effect at week 6			Short term effect at week 1			Sustained effect after the intervention	
	Mean difference (95% CI) in change	*p*	ES	Mean difference (95% CI) in change	*p*	ES	Mean difference (95% CI) in change	*p*
SenseWear, daytime								
Skin temperature (°C)	0.02 (-0.79, 0.83)	0.957		0.54 (-0.13, 1.22)	0.167		-0.10 (-0.78, 0.59)	0.781
Distance (kilometers)	0.02 (-0.06, 0.10)	0.283		0.01 (-0.10, 0.12)	0.522		-0.01 (-0.06, 0.05)	0.705
Step counter (n)	42.83 (-43.87, 129.53)	0.277		69.25 (-16.87, 155.37)	0.177		24.01 (-30.21, 80.23)	0.435
Lying down (hrs)	-1.49 (-3.12, 0.15)	0.139		-0.49 (-1.89, 0.90)	0.968		-1.14 (-2.74, 0.46)	0.491
Average MET	-0.02 (-0.10, 0.06)	0.298		-0.02 (-0.71, 0.68)	0.647		-0.11 (-0.32, 0.09)	0.397
Physical activity (hrs)	0.26 (-0.35, 0.86)	0.403		0.01 (-0.79, 0.82,)	0.973		-0.14 (-0.67, 0.39)	0.603
EE (kcal)	317.88 (-349.43, 985.18)	0.235		394.15 (-353.81, 1142.12)	0.286		252.92 (-527.63, 11033.47)	0.477
Awake (hrs)	**1.91 (0.09, 3.73)**	**0.042**	**0.655**	1.01 (-1.08, 3.11)	0.676		1.72 (-0.63, 4.07)	0.548
Total sleep (hrs)	**-1.35 (-2.65, -0.05)**	**0.040**	**0.664**	-0.09 (-1.13, 0.95)	0.819		-1.15 (-2.28, 0.03)	0.651
Light sleep (hrs)	**-1.27 (-2.36, -0.19)**	**0.023**	**0.746**	-0.18 (-0.96, 0.61)	0.873		-0.68 (-1.88, 0.52)	0.779
Deep sleep (hrs)	0.06 (-0.41, 0.29)	0.281		0.00 (-0.43, 0.43)	0.497		-0.20 (-0.50, 0.10)	0.861
Very deep sleep (hrs)	-0.02 (-0.26, 0.21)	0.712		0.09 (-0.15, 0.33)	0.819		-0.16 (-0.42, 0.09)	0.734

Outcomes	PARO intervention effect at week 6			Short term effect at week 1			Sustained effect after the intervention	
	Mean difference (95% CI) in change	*p*	ES	Mean difference (95% CI) in change	*p*	ES	Mean difference (95% CI) in change	*p*
SenseWear, nighttime								
Skin temperature (°C)	0.09 (-4.48, 4.66,)	0.584		0.56 (-3.98, 5.11)	0.361		0.31 (-0.40, 1.02)	0.544
Distance (kilometers)	0.17 (-0.13, 0.46)	0.598		0.02 (-0.03, 0.07)	0.603		0.02 (-0.04, 0.07)	0.336
Step counter (n)	10.7.78 (-63.74, 279.30)	0.565		65.50 (-873.97, 139.73)	0.754		56.94 (-30.14, 144.02)	0.785
Lying down (hrs)	-0.49 (-3.43, 2.45)	0.738		0.91 (-1.94, 3.76)	0.522		-1.15 (-3.60, 1.31)	0.915
Average MET	-0.01 (-0.19, 0.16)	0.938		-0.05 (-0.25, 0.14)	0.835		-0.07 (-0.28, 0.14)	0.476
Physical activity (hrs)	0.14 (-0.23, 0.51)	0.452		0.23 (-0.19, 0.64)	0.280		0.11 (-0.28, 0.50)	0.568
EE (kcal)	-320.03 (-1134.10, 494.03)	0.346		26.77 (-767.30, 820.84)	0.936		-197.43 (-915.64, 520.79)	0.702
Awake (hrs)	-0.98 (-3.19, 1.22)	0.298		-1.20 (-2.99, 0.60)	0.146		0.27 (-1.60, 2.13)	0.799
Total sleep (hrs)	-0.37 (-3.04, 2.30)	0.781		0.97 (-1.67, 3.62)	0.462		-0.41 (-3.04, 2.22)	0.747
Light sleep (hrs)	0.38 (-1.76, 2.52)	0.720		**1.81 (0.22, 3.84)**	**0.030**	**0.57**	-0.39 (-2.09, 1.32)	0.811
Deep sleep (hrs)	-0.8 (-1.61, 0.25)	0.162		-0.33 (-1.03, 0.37)	0.344		-0.47 (-1.11, 0.18)	0.206
Very deep sleep (hrs)	-0.07 (-0.88, 0.73)	0.464		-0.51 (-1.24, 0.23)	0.753		-0.34 (-2.32, 0.26)	0.770

Abbreviations: hrs, hours; mins, minutes; EE, energy expenditure; MET, metabolic equivalent; ES, the effect size was calculated by Cohen's *d;* Bolded values indicate statistically significant results at the level of $p<0.05$.
Short term effect means the change on Monday at week 1, sustained effect means the change on Saturday at week 6.

[#] Values were calculated with the generalized estimating equation model adjusted for gender and imbalanced baseline value. Change scores reflected the difference between the given assessment time-point and the values recorded at week 0 baseline.
Mean difference between groups = Mean difference in the intervention group - Mean difference in the control group, positive scores in favour of PARO group for daytime skin temperature, distance, step counter, physical activity, average MET, energy expenditure, awake and night-time lying down and sleep; negative scores in favour of PARO group for daytime lying down, sleep and nighttime skin temperature, distance, step counter, physical activity, average MET, energy expenditure, and awake.